

510(K) SUMMARY

APR 17 2014

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

The assigned 510(k) number is: k133522

1. Submitter's Identification:

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Date Summary Prepared: April 15, 2014

2. Name of the Device:

Rightest Blood Glucose Monitoring System GM700
Rightest Blood Glucose Monitoring System GM650
Rightest Blood Glucose Monitoring System GM300
GE300 Talking Blood Glucose Monitoring System
GE200 Blood Glucose Monitoring System
Bionime Rightest Diabetes Management System
GE Diabetes Management System

3. Common or Usual Name:

Device Name	Product Code	Classification	Regulation	Panel
Glucose Test System	NBW: Blood Glucose Test System, Over-the-Counter	Class II	21 CFR § 862.1345	Clinical Chemistry (75)
Glucose Test System	LFR: Glucose Dehydrogenase, Glucose	Class II	21 CFR § 862.1345	Clinical Chemistry (75)
Glucose Test System	CGA: Glucose Oxidase, Glucose	Class II	21 CFR § 862.1345	Clinical Chemistry (75)
Calculator/Data Processing Module	JQP: Calculator/ Data Processing Module for	Class I	21 CFR § 862.2100	Clinical Chemistry

for Clinical Use	Clinical Use			(75)
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4. **Device Description:**

- 4.1 Rightest Blood Glucose Monitoring System GM700 consists of following devices: Rightest Blood Glucose Meter GM700, Rightest Blood Glucose Test Strip GS700, Rightest Control Solution GC700, lancing device and sterile lancets. The Rightest Blood Glucose Meter GM700, when used with the Rightest Blood Glucose Test Strips GS700, quantitatively measures glucose in fresh capillary whole blood. The performance of the Rightest Blood Glucose Monitoring System GM700 is verified by the Rightest Control Solution GC700.
- 4.2 Rightest Blood Glucose Monitoring System GM650 consists of following devices: Rightest Blood Glucose Meter GM650, Rightest Blood Glucose Test Strip GS650, Rightest Control Solution GC650, lancing device and sterile lancets. The Rightest Blood Glucose Meter GM650, when used with the Rightest Blood Glucose Test Strips GS650, quantitatively measures glucose in fresh capillary whole blood. The performance of the Rightest Blood Glucose Monitoring System GM650 is verified by the Rightest Control Solution GC650.
- 4.3 Rightest Blood Glucose Monitoring System GM300 consists of following devices: Rightest Blood Glucose Meter GM300, Rightest Blood Glucose Test Strip GS300, Rightest Control Solution GC300, lancing device and sterile lancets. The Rightest Blood Glucose Meter GM300, when used with the Rightest Blood Glucose Test Strips GS300, quantitatively measures glucose in fresh capillary whole blood. The performance of the Rightest Blood Glucose Monitoring System GM300 is verified by the Rightest Control Solution GC300.
- 4.4 GE200 Blood Glucose Monitoring System consists of following devices: GE200 Blood Glucose Meter, GE200 Blood Glucose Test Strip, GE200 Control Solution, lancing device and sterilized lancets. The GE200 Blood Glucose Meter, when used with the GE200 Blood Glucose Test Strips, quantitatively measures glucose in fresh capillary whole blood. The performance of the GE200 Blood Glucose Monitoring System is verified by the GE200 Control Solution
- 4.5 GE300 Talking Blood Glucose Monitoring System consists of following devices: GE300 Talking Blood Glucose Meter, GE300 Talking Blood Glucose Test Strip, GE300 Series Control Solution, lancing device and sterile lancets. The GE300 Talking Blood Glucose Meter, when used with the GE300 Talking Blood Glucose Test Strips, quantitatively measures glucose in fresh capillary whole blood. The performance of the GE300 Talking Blood Glucose Monitoring System is verified by the GE300 Series Control Solution.

The following devices have already been cleared. The purpose of this submission is to add additional compatible meters for use with these systems.

- 4.6 The Bionime Rightest Diabetes Management System allows the transfer of blood glucose readings from a compatible Rightest Glucose meter to a PC via PC link adapter (through USB and wireless connection).

The Data analysis features enable the user(s) to view and analyze blood glucose readings from different meal time periods. Other features including data tables, trend charts, pie charts, and printed reports are available for viewing and analyzing these readings within the different time slots.

The revised system includes: 1) Installation CD with setup files for Rightest GP200 Diabetes Management Software and Rightest PC Link Adapter Driver, 2) One or multiple Rightest Adapters: GP550, GP700, GP650 and GP300

Compatible Meters include: GM250, GM550, GM700, GM650 and GM300.

- 4.7 The GE Diabetes Management System allows the transfer of blood glucose readings from a compatible GE Glucose meter to a PC via PC link adapter (through USB and wireless connection).

The Data analysis features enable the user(s) to view and analyze blood glucose readings from different meal time periods. Other features including data tables, trend charts, pie charts, and printed reports are available for viewing and analyzing these readings within the different time slots.

The revised system includes: 1) Installation CD with setup files for GE GP200 Diabetes Management Software and GE PC Link Adapter Driver, 2) One or multiple GE Adapters: GE GP550, GE GP700 and GE GP300.

Compatible Meters include: GE100, GE200 and GE300.

5. Intended Use/Indications for Use:

The Rightest and GE Diabetes Management System Software has been previously cleared by FDA under k113007 and k113007/A001, respectively.

a. Bionime Rightest Diabetes Management System

The Bionime Rightest Diabetes Management System is an over-the-counter software system for use by Health Care Professionals and Patients with diabetes as an aid for managing diabetes. User(s) can transfer blood glucose readings from the following glucose meters: Rightest Blood Glucose Monitoring System GM550 and GM250 with Rightest PC Link Adaptor (GP550), Rightest Blood Glucose Monitoring System GM700 with Rightest PC Link Adaptor (GP550) or Rightest Bluetooth PC Link (GP700), Rightest Blood Glucose Monitoring System GM650 with Rightest PC Link Adaptor for GM650 (GP650), and Rightest Blood Glucose Monitoring System GM300 with Rightest PC Link Adaptor for GM300 (GP300) to a personal computer

for the purpose of viewing, analyzing and printing the blood glucose readings, as well as to backup and to recover users' profile and data.

The Bionime Rightest Diabetes Management System is not intended to provide treatment decisions, nor should it substitute professional opinion. All medical diagnoses and treatment plans should be performed by a licensed healthcare professional.

b. GE Diabetes Management System

The GE Diabetes Management System is an over-the-counter software system for use by Health Care Professionals and Patients with diabetes as an aid for managing diabetes. User(s) can transfer blood glucose readings from the following glucose meters: GE100 Blood Glucose Monitoring System with GE PC Link Adaptor (GE GP550), GE300 Talking Blood Glucose Monitoring System with GE PC Link Adaptor for GE300 (GE GP300) or GE200 Blood Glucose Monitoring System with GE PC Link Adaptor (GE GP550 and GE Bluetooth PC Link (GE GP700) to a personal computer for the purpose of viewing, analyzing and printing the blood glucose readings, as well as to backup and to recover users' profile and data.

The GE Diabetes Management System is not intended to provide treatment decisions, nor should it substitute professional opinion. All medical diagnoses and treatment plans should be performed by a licensed health care professional.

c. Rightest Blood Glucose Monitoring System GM700:

The Rightest Blood Glucose Monitoring System GM700 is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips, forearm or palm. The Rightest Blood Glucose Monitoring System GM700 is intended to be used by a single person and should not be shared.

The Rightest Blood Glucose Monitoring System GM700 is intended for self testing outside the body (in vitro diagnostic use) by people with diabetes at home as an aid to monitor the effectiveness of diabetes control. The Rightest Blood Glucose Monitoring System GM700 should not be used for the diagnosis of, or screening for diabetes or for neonatal use. Alternative site testing should be done only during steady - state times (when glucose is not changing rapidly).

The Rightest Blood Glucose Test Strips GS700 are for use with the Rightest Blood Glucose Meter GM700 to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips, forearm or palm.

d. Rightest Blood Glucose Monitoring System GM650:

The Rightest Blood Glucose Monitoring System GM650 is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips, forearm or palm. The Rightest Blood Glucose Monitoring System GM650 is intended to be used by a single person and should not be shared.

The Rightest Blood Glucose Monitoring System GM650 is intended for self testing outside the body (in vitro diagnostic use) by people with diabetes at home as an aid to monitor the effectiveness of diabetes control. The Rightest Blood Glucose Monitoring System GM650 should not be used for the diagnosis of, or screening for diabetes or for neonatal use. Alternative site testing should be done only during steady - state times (when glucose is not changing rapidly).

The Rightest Blood Glucose Test Strips GS650 are for use with the Rightest Blood Glucose Meter GM650 to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips, forearm or palm.

e. Rightest Blood Glucose Monitoring System GM300:

The Rightest Blood Glucose Monitoring System GM300 is intended for in vitro diagnostic use (outside of body). It is indicated to be used by professional healthcare personnel or diabetes at home to measure the glucose concentration for aiding diabetes management. The glucose concentration is measured with quantitative capillary whole blood from the fingertip, palm, and forearm by using Rightest Blood Glucose Monitoring System GM300. This device is not intended for testing neonate blood samples.

Special conditions for use statement(s): Rightest System provides plasma equivalent results.

f. GE200 Blood Glucose Monitoring System:

The GE200 Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips, forearm or palm. The GE200 Blood Glucose Monitoring System is intended to be used by a single person and should not be shared.

The GE200 Blood Glucose Monitoring System is intended for self testing outside the body (in vitro diagnostic use) by people with diabetes at home as an aid to monitor the effectiveness of diabetes control. The GE200 Blood Glucose Monitoring System should not be used for the diagnosis of, or screening for diabetes or for neonatal use. Alternative site testing should be done only during steady - state times (when glucose is not changing rapidly).

The GE200 Blood Glucose Test Strips are for use with the GE200 Blood Glucose Meter to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips, forearm or palm.

g. GE300 Talking Blood Glucose Monitoring System:

The GE300 Talking Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips, forearm or palm. The GE300 Talking Blood Glucose Monitoring System is intended to be used by a single person and should not be shared.

The GE300 Talking Blood Glucose Monitoring System is intended for self testing outside the body (in vitro diagnostic use) by people with diabetes at home as an aid to monitor the effectiveness of diabetes control. The GE300 Talking Blood Glucose Monitoring System should not be used for the diagnosis of, or screening for diabetes or for neonatal use. Alternative site testing should be done only during steady - state times (when glucose is not changing rapidly).

The GE300 Blood Glucose Test Strip is for use with the GE300 Talking Blood Glucose Meter to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips, forearm or palm.

6. Predicate Device Information:

The Rightest Blood Glucose Monitoring System and GE Blood Glucose Monitoring System are substantially equivalent to the predicate device noted below.

Name: Rightest Blood Glucose Monitoring System GM700
Device Company: Bionime Corporation
510(K) Number: K110737 and K123008

Name: Rightest Blood Glucose Monitoring System GM650
Device Company: Bionime Corporation
510(K) Number: K120423 and K123008

Name: Rightest Blood Glucose Monitoring System GM300
Device Company: Bionime Corporation
510(K) Number: K062567

Name: GE200 Blood Glucose Monitoring System
Device Company: Bionime Corporation
510(K) Number: K123008

Name: GE300 Talking Blood Glucose Monitoring System
Device Company: Bionime Corporation

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510(K) Number: K120423 and K123008

The Rightest Diabetes Management System and the GE Diabetes Management System are substantially equivalent to the predicate device noted below.

Name: Bionime Diabetes Management System
 Device Company: Bionime Corporation
 510(K) Number: K113007

Name: GE Diabetes Management System
 Device Company: Bionime Corporation
 510(K) Number: K113007/A001

7. Comparison to Predicate Devices:

Specification Comparison

Item	Subject Device		Predicate Device	
	Bionime Rightest Diabetes Management System	GE Diabetes Management System	Bionime Diabetes Management System (BDMS)	GE Diabetes Management System
Similarities				
Intended use/ Indication(s) for use	Same		BDMS is intended for use by Health Care professionals and patients with diabetes. When it is installed on a personal computer (PC), a database can be used to store multiple users' profiles and manage their blood glucose readings. People who use BDMS must login to their own profile. BDMS enables users to view and organize the blood glucose readings which are uploaded from Rightest Glucose meter(s). Users can backup and recover their profiles and print blood glucose data and report from their PC.	
COM Ports scan	Same		Automatic scan for connected ports	
Multiple patients	Same		Can list data for multiple patients	
Data list/ Summary report	Same		List all readings inside selected time frame	
Target periods	Same		Daily time periods can be changed	
Average week	Same		7-day report	
Average Day	Same		1-day report	
Password	Same		Does not have password protection on the software	
Providers	Same		Does not have providers but does allow for multiple databases	
Reports and charts	Same		Data List, Standard Day report, Trend report, Pie charts	

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Change Meter settings	Same	Does not allow change to meter settings through the Diabetes Management System
Operating System	Same	Windows XP Professional™ Windows Vista Professional™ Windows 7 Professional™
Associate a meter to a person	Same	Does not associate a meter to a person
Standard week report	Same	No standard week report

Additional Adapters and compatible meters to be added under this application (Rightest Diabetes Management System):

Table 1

Item	Subject Pairs (Meter / Adapter)		Predicate (Meter / Adapter)	
	Meter	Adapter	Meter	Adapter
New pair 1	Rightest GM700	GP550	Rightest GM700 (K110737/K123008)	GP550
Similarities/Differences				
Operation	The meter connected to the adapter by plug in and transmit data to computer.		Same	
Connection	Mini USB port	Plug in to meter USB Port	Same	Same
Function	A device of quantitative glucose measuring system.	A device to transmit data from meter.	Same	Same
Feature	Up to 1000 data stored	Cable	Same	Same
Appearance	A meter with a display window, two side buttons, one main button, and a test strip port.	A connector to meter and computer	Same	Same
Minimum Sample Volume	0.75 µL	None Applicable	Same	None Applicable
Test Time	5 seconds	None Applicable	Same	None Applicable
Measuring Range	20-600 mg/dL	None Applicable	Same	None Applicable
Operating Relative Humidity Range	10-90%	None Applicable	Same	None Applicable
Memory Capacity	1000 blood glucose test results with date and time	None Applicable	Same	None Applicable
Coding	Auto Coding	None Applicable	Same	None Applicable
Meter Storage Conditions	14 ~140 ° (-10 ~ 60 °)	None Applicable	Same	None Applicable
Test Strip Storage Conditions	39 ~86 ° (4 ~ 30 °), < 90 % relative humidity	None Applicable	Same	None Applicable
The unit of measurement data	Fix on mg/dL	None Applicable	Same	None Applicable

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Sample	Capillary whole blood	None Applicable	Same	None Applicable
Interference	Uric acid ≥ 16 mg/dL Xylose ≥ 10 mg/dL Ascorbic acid ≥ 3 mg/dL Dopamine HCl ≥ 1.25 mg/dL L-Dopa ≥ 2 mg/dL	None Applicable	Same	None Applicable
Voice Function	No	None Applicable	Same	None Applicable
Strip Reagent	1.FAD-glucose Dehydrogenase (FAD-GDH) 12.1% 2.Potassium ferricyanide 48.5% 3.Non-reactive ingredients 39.4%	None Applicable	Same	None Applicable
Measurement Technology	Dehydrogenase Electrochemical Sensor	None Applicable	Same	None Applicable
Operating Temperature Range	43 ~ 111 ° (6 ~ 44 °)	None Applicable	Same	None Applicable
Compatible to DMS	Compatible to Bionime Rightest Diabetes Management System	Compatible to Bionime Rightest Diabetes Management System	None Applicable	Same

Table 2

Item	Subject Pairs (Meter / Adapter)		Predicate (Meter / Adapter)	
	Meter	Adapter	Meter	Adapter
New pair 2	Rightest GM700	GP700 (Bluetooth)	Rightest GM700 (K110737/K123008)	GP550
Similarities/Differences				
Operation	The meter connected to the adapter by plug in and transmit data to computer.		Same	
Connection	Mini USB port	Plug in to meter USB Port	Same	Same
Function	A device of quantitative glucose measuring system.	A device to transmit data from meter.	Same	Same
Feature	Up to 1000 data stored	Wireless	Same	Cable
Appearance	A meter with a display window, two side buttons, one main button, and a test strip port.	A connector to meter.	Same	A connector to meter and computer
Minimum Sample Volume	0.75 μ L	None Applicable	Same	None Applicable
Test Time	5 seconds	None Applicable	Same	None Applicable

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Measuring Range	20-600 mg/dL	None Applicable	Same	None Applicable
Operating Relative Humidity Range	10-90%	None Applicable	Same	None Applicable
Memory Capacity	1000 blood glucose test results with date and time	None Applicable	Same	None Applicable
Coding	Auto Coding	None Applicable	Same	None Applicable
Meter Storage Conditions	14 ~140 °F (-10 ~ 60°C)	None Applicable	Same	None Applicable
Test Strip Storage Conditions	39 ~86 °F (4 ~ 30°C), < 90% relative humidity	None Applicable	Same	None Applicable
The unit of measurement data	Fix on mg/dL	None Applicable	Same	None Applicable
Sample	Capillary whole blood	None Applicable	Same	None Applicable
Interference	Uric acid \geq 16 mg/dL Xylose \geq 10 mg/dL Ascorbic acid \geq 3 mg/dL Dopamine HCl \geq 1.25 mg/dL L-Dopa \geq 2 mg/dL	None Applicable	Same	None Applicable
Voice Function	No	None Applicable	Same	None Applicable
Strip Reagent	1.FAD-glucose Dehydrogenase (FAD-GDH) 12.1% 2.Potassium ferricyanide 48.5% 3.Non-reactive ingredients 39.4%	None Applicable	Same	None Applicable
Measurement Technology	Dehydrogenase Electrochemical Sensor	None Applicable	Same	None Applicable
Operating Temperature Range	43 ~111 °F (6 ~ 44°C)	None Applicable	Same	None Applicable
Compatible to DMS	Compatible to Bionime Rightest Diabetes Management System	Compatible to Bionime Rightest Diabetes Management System	None Applicable	Same

Table 3

Item	Subject Pairs (Meter / Adapter)		Predicate (Meter / Adapter)	
	Meter	Adapter	Meter	Adapter
New pair 3	Rightest GM650	GP650 (USB)	Rightest GM650 (K120423/K123008)	GP550
Similarities/Differences				
Operation	The meter connected to the adapter by plug in		Same	

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	and transmit data to computer.			
Feature	Up to 500 data stored	Cable	Same	Same
Function	A device of quantitative glucose measuring system.	A device to transmit data from meter.	Same	Same
Appearance	A meter with a display window, two side buttons, one main button, and a test strip port.	A connector to meter and computer	Same	Same
Connection	Far-red sensor	Plug in	Same	Same
Minimum Sample Volume	0.75 μ L	None Applicable	Same	None Applicable
Test Time	5 seconds	None Applicable	Same	None Applicable
Measuring Range	20-600 mg/dL	None Applicable	Same	None Applicable
Operating Relative Humidity Range	10-90%	None Applicable	Same	None Applicable
Memory Capacity	500 blood glucose test results with date and time	None Applicable	Same	None Applicable
Coding	Auto Coding	None Applicable	Same	None Applicable
Meter Storage Conditions	14 ~140 °F (-10 ~ 60°C)	None Applicable	Same	None Applicable
Test Strip Storage Conditions	39 ~86 °F (4 ~ 30°C), < 90% relative humidity	None Applicable	Same	None Applicable
The unit of measurement data	Fix on mg/dL	None Applicable	Same	None Applicable
Sample	Capillary whole blood	None Applicable	Same	None Applicable
Interference	Uric acid \geq 16 mg/dL Xylose \geq 10 mg/dL Ascorbic acid \geq 3 mg/dL Dopamine HCl \geq 1.25 mg/dL L-Dopa \geq 2 mg/dL	None Applicable	Same	None Applicable
Voice Function	Yes	None Applicable	Same	None Applicable
Strip Reagent	1.FAD-glucose Dehydrogenase (FAD-GDH) 12.1% 2.Potassium ferricyanide 48.5% 3.Non-reactive ingredients 39.4%	None Applicable	Same	None Applicable
Measurement Technology	Dehydrogenase Electrochemical Sensor	None Applicable	Same	None Applicable
Operating Temperature Range	43 ~111 °F (6 ~ 44°C)	None Applicable	Same	None Applicable
Compatible to DMS	Compatible to Bionime Rightest Diabetes Management System	Compatible to Bionime Rightest Diabetes Management System	None Applicable	Same

Table 4

Item	Subject Pairs (Meter / Adapter)		Predicate (Meter / Adapter)	
	Meter	Adapter	Meter	Adapter
New pair 4	Rightest GM300	GP300 (USB)	Rightest GM300, (K062567)	GP550
Similarities/Differences				
Operation	The meter connected to the adapter by plug in and transmit data to computer.		Same	
Function	A device of quantitative glucose measuring system.	A device to transmit data from meter.	Same	Same
Appearance	A meter with a display window, two side buttons, one main button, and a test strip port.	A connector to meter and computer	Same	Same
Connection	Code key base	Plug in	Same	Same
Feature	Up to 300 data stored	Cable	Same	Same
Minimum Sample Volume	1.4 μ L	None Applicable	Same	None Applicable
Test Time	8 seconds	None Applicable	Same	None Applicable
Measuring Range	20-600 mg/dL	None Applicable	Same	None Applicable
Operating Relative Humidity Range	10-90%	None Applicable	Same	None Applicable
Memory Capacity	300 blood glucose test results with date and time	None Applicable	Same	None Applicable
Coding	Code Key	None Applicable	Same	None Applicable
Meter Storage Conditions	14 ~140 °F (-10 ~ 60°C)	None Applicable	Same	None Applicable
Test Strip Storage Conditions	39 ~86 °F (4 ~ 30°C), < 90% relative humidity	None Applicable	Same	None Applicable
The unit of measurement data	Fix on mg/dL	None Applicable	Same	None Applicable
Sample	Capillary whole blood	None Applicable	Same	None Applicable
Interference	Uric acid \geq 9 mg/dL Methyldopa \geq 1.5 mg/dL Cholesterol \geq 250 mg/dL L-Dopa \geq 1.5 mg/dL	None Applicable	Same	None Applicable
Voice Function	No	None Applicable	Same	None Applicable
Strip Reagent	1.Glucose Oxidase 8.5% 2.Potassium ferricyanide	None Applicable	Same	None Applicable

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	48.5% 3.Non-reactive ingredients 43%			
Measurement Technology	Glucose Oxidase Electrochemical Sensor	None Applicable	Same	None Applicable
Operating Temperature Range	50 ~104 °F (10 ~ 40°C)	None Applicable	Same	None Applicable
Compatible to DMS	Compatible to Bionime Rightest Diabetes Management System	Compatible to Bionime Rightest Diabetes Management System	None Applicable	Same

Additional Adapters and compatible meters to be added under this application (GE Diabetes Management System):

Table 5

Item	Subject Pairs (Meter / Adapter)		Predicate (Meter / Adapter)	
	Meter	Adapter	Meter	Adapter
New pair 1	GE200	GE GP550 (USB)	GE200 (K123008)	GE GP550
Similarities/Differences				
Operation	The meter connected to the adapter by plug in and transmit data to computer.		Same	
Connection	Mini USB port	Plug in	Same	Same
Function	A device of quantitative glucose measuring system.	A device to transmit data from meter.	Same	Same
Feature	Up to 1000 data stored	Cable	Same	Same
Appearance	A meter with a display window, two side buttons, one main button, and a test strip port.	A connector to meter and computer	Same	Same
Minimum Sample Volume	0.75 µL	None Applicable	Same	None Applicable
Test Time	5 seconds	None Applicable	Same	None Applicable
Measuring Range	20-600 mg/dL	None Applicable	Same	None Applicable
Operating Relative Humidity Range	10-90%	None Applicable	Same	None Applicable
Memory Capacity	1000 blood glucose test results with date and time	None Applicable	Same	None Applicable
Coding	Auto Coding	None Applicable	Same	None Applicable
Meter Storage Conditions	14 ~140 °F (-10 ~ 60°C)	None Applicable	Same	None Applicable
Test Strip Storage Conditions	39 ~86 °F (4 ~ 30°C), < 90% relative humidity	None Applicable	Same	None Applicable
The unit of measurement	Fix on mg/dL	None Applicable	Same	None Applicable

data				
Sample	Capillary whole blood	None Applicable	Same	None Applicable
Interference	Uric acid ≥ 16 mg/dL Xylose ≥ 10 mg/dL Ascorbic acid ≥ 3 mg/dL Dopamine HCl ≥ 1.25 mg/dL L-Dopa ≥ 2 mg/dL	None Applicable	Same	None Applicable
Voice Function	No	None Applicable	Same	None Applicable
Strip Reagent	1.FAD-glucose Dehydrogenase (FAD-GDH) 12.1% 2.Potassium ferricyanide 48.5% 3.Non-reactive ingredients 39.4%	None Applicable	Same	None Applicable
Measurement Technology	Dehydrogenase Electrochemical Sensor	None Applicable	Same	None Applicable
Operating Temperature Range	43 ~111 °F (6 ~ 44°C)	None Applicable	Same	None Applicable
Compatible to DMS	Compatible to GE Diabetes Management System	Compatible to GE Diabetes Management System	None Applicable	Same

Table 6

Item	Subject Pairs (Meter / Adapter)		Predicate (Meter / Adapter)	
	Meter	Adapter	Meter	Adapter
New pair 2	GE200	GE GP700 (Bluetooth)	GE200 (K123008)	GE GP550
Similarities/Differences				
Operation	The meter connected to the adapter by plug in and transmit data to computer.		Same	
Connection	Mini USB port	Plug in	Same	Same
Function	A device of quantitative glucose measuring system.	A device to transmit data from meter.	Same	Same
Feature	Up to 1000 data stored	Wireless	Same	Cable
Appearance	A meter with a display window, two side buttons, one main button, and a test strip port.	A connector to meter.	Same	A connector to meter and computer
Minimum Sample Volume	0.75 μ L	None Applicable	Same	None Applicable
Test Time	5 seconds	None Applicable	Same	None Applicable
Measuring Range	20-600 mg/dL	None Applicable	Same	None Applicable

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Operating Relative Humidity Range	10-90%	None Applicable	Same	None Applicable
Memory Capacity	1000 blood glucose test results with date and time	None Applicable	Same	None Applicable
Coding	Auto Coding	None Applicable	Same	None Applicable
Meter Storage Conditions	14 ~140 °F (-10 ~ 60°C)	None Applicable	Same	None Applicable
Test Strip Storage Conditions	39 ~86 °F (4 ~ 30°C), < 90% relative humidity	None Applicable	Same	None Applicable
The unit of measurement data	Fix on mg/dL	None Applicable	Same	None Applicable
Sample	Capillary whole blood	None Applicable	Same	None Applicable
Interference	Uric acid \geq 16 mg/dL Xylose \geq 10 mg/dL Ascorbic acid \geq 3 mg/dL Dopamine HCl \geq 1.25 mg/dL L-Dopa \geq 2 mg/dL	None Applicable	Same	None Applicable
Voice Function	No	None Applicable	Same	None Applicable
Strip Reagent	1.FAD-glucose Dehydrogenase (FAD-GDH) 12.1% 2.Potassium ferricyanide 48.5% 3.Non-reactive ingredients 39.4%	None Applicable	Same	None Applicable
Measurement Technology	Dehydrogenase Electrochemical Sensor	None Applicable	Same	None Applicable
Operating Temperature Range	43 ~111 °F (6 ~ 44°C)	None Applicable	Same	None Applicable
Compatible to DMS	Compatible to GE Diabetes Management System	Compatible to GE Diabetes Management System	None Applicable	Same

Table 7:

Item	Subject Pairs (Meter / Adapter)		Predicate (Meter / Adapter)	
	Meter	Adapter	Meter	Adapter
New pair 3	GE300	GE GP300 (USB)	GE300 (K120423/K123008)	GE GP550
Similarities/Differences				
Operation	The meter connected to the adapter by plug in and transmit data to computer.		Same	
Feature	Up to 500 data stored	Cable	Same	Same
Function	A device of quantitative glucose measuring system.	A device to transmit data from meter.	Same	Same
Appearance	A meter with a display window, two side buttons, one main button, and a test strip port.	A connector to meter and computer	Same	Same
Connection	Far-red sensor	Plug in	Same	Same
Minimum Sample Volume	0.75 μ L	None Applicable	Same	None Applicable
Test Time	5 seconds	None Applicable	Same	None Applicable
Measuring Range	20-600 mg/dL	None Applicable	Same	None Applicable
Operating Relative Humidity Range	10-90%	None Applicable	Same	None Applicable
Memory Capacity	500 blood glucose test results with date and time	None Applicable	Same	None Applicable
Coding	Auto Coding	None Applicable	Same	None Applicable
Meter Storage Conditions	14 ~140 °F (-10 ~ 60°C)	None Applicable	Same	None Applicable
Test Strip Storage Conditions	39 ~86 °F (4 ~ 30°C), < 90% relative humidity	None Applicable	Same	None Applicable
The unit of measurement data	Fix on mg/dL	None Applicable	Same	None Applicable
Sample	Capillary whole blood	None Applicable	Same	None Applicable
Interference	Uric acid \geq 16 mg/dL Xylose \geq 10 mg/dL Ascorbic acid \geq 3 mg/dL Dopamine HCl \geq 1.25 mg/dL L-Dopa \geq 2 mg/dL	None Applicable	Same	None Applicable
Voice Function	Yes	None Applicable	Same	None Applicable
Strip Reagent	1.FAD-glucose Dehydrogenase (FAD-GDH) 12.1%	None Applicable	Same	None Applicable

	2.Potassium ferricyanide 48.5% 3.Non-reactive ingredients 39.4%			
Measurement Technology	Dehydrogenase Electrochemical Sensor	None Applicable	Same	None Applicable
Operating Temperature Range	43 ~111 °F (6 ~ 44°C)	None Applicable	Same	None Applicable
Compatible to DMS	Compatible to GE Diabetes Management System	Compatible to GE Diabetes Management System	None Applicable	Same

8. Discussion of Non-Clinical and Clinical Tests Performed for Determination of Substantial Equivalence:

Verification and validation of test results were evaluated to establish the performance, functionality and reliability of the Rightest Diabetes Management System, and the GE Diabetes Management System when used with the following systems: Rightest Blood Glucose Monitoring System GM700, Rightest Blood Glucose Monitoring System GM650, Rightest Blood Glucose Monitoring System GM300, GE300 Talking Blood Glucose Monitoring System, and GE200 Blood Glucose Monitoring System

Data Transmission Memory Rollover Synchronization Verification

Data transmission accuracy and memory data rollover synchronization were tested at each meter's full data memory capacity to ensure successful upload and storage into software database of the Rightest/GE Diabetes Management System. Software test used 3 meters per adapter.

Meter/Adapter	Expected Test Result	Result
Rightest GM700 Meter/ GP550 Adapter (USB)	Full set of data (1000 records) transferred from meter to software was accurately downloaded Meter memory data rollover accurately transmitted to Rightest DMS with additional new data	Pass
Rightest GM700 Meter/ GP700 Adapter (Bluetooth)	Full set of data (1000 records) transferred from meter to software was accurately downloaded Meter memory data rollover accurately transmitted to Rightest DMS with additional new data	Pass
Rightest GM650 Meter/ GP650 Adapter (USB)	Full set of data (500 records) transferred from meter to software was accurately downloaded	Pass

	Meter memory data rollover accurately transmitted to Rightest DMS with additional new data	
Rightest GM300 Meter/ GP300 Adapter (USB)	Full set of data (300 records) transferred from meter to software was accurately downloaded Meter memory data rollover accurately transmitted to Rightest DMS with additional new data	Pass
GE200 Meter/ GEGP550 (USB)	Full set of data (1000 records) transferred from meter to software was accurately downloaded Meter memory data rollover accurately transmitted to GE DMS with additional new data	Pass
GE200 Meter/ GEGP700 (Bluetooth)	Full set of data (1000 records) transferred from meter to software was accurately downloaded Meter memory data rollover accurately transmitted to GE DMS with additional new data	Pass
GE300 Meter/ GEGP300 (USB)	Full set of data (500 records) transferred from meter to software was accurately downloaded Meter memory data rollover accurately transmitted to GE DMS with additional new data	Pass

User Performance Evaluation:

The User (Layperson) Performance Evaluation of PC Link Adapters study included 45 participants of varying age, sex, background, education level, and work experience. The study was conducted from October to December 2013.

The study demonstrates that English-speaking/reading laypersons are able to follow user instructions for the PC link adapters and Software user manual to successfully connect PC Link Adapters and paired meter to PC installed and import data to GP200 Diabetes Management Software.

Electromagnetic Compatibility (EMC):

To evaluate the compliance of safety requirements for electrical equipment – PC Adapters (GP300, GP650, and GP700), the testing and compliance reports were performed by SGS Taiwan Electronics & Communication Laboratory.

The EMC reports confirmed that each PC Adapter met performance criteria indicated by the standards.

Readability Assessment:

The Readability Assessment Tests were performed using the Flesch-Kincaid Grade Level Score to evaluate the readability of the PC Adapter Guides and PC Adapter User Manuals for both Rightest BDMS and GE DMS Software.

The obtained results demonstrate that PC Adapter Guides and PC Adapter User Manuals for both Rightest BDMS and GE DMS Software each received a Flesch-Kincaid Grade Level that indicates each text is expected to be understood by an average student in the eighth grade. The assessments ranged from 6.2 to 7.4 and therefore each text meets the criteria.

9. Conclusion:

Results of performance evaluation of the Rightest Diabetes Management System and the GE Diabetes Management System with addition of compatible blood glucose meters and their respective PC Link Adapters demonstrate that the subject devices are substantially equivalent to the predicate devices.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

April 17, 2014

BIONIME COPORATION
C/O FENG-YU LEE
2700 LA PAZ ROAD
SUITE 266B
MISSION VIEJO CA 92691

Re: K133522

Trade/Device Name: Rightest Blood Glucose Monitoring System GM700
Rightest Blood Glucose Monitoring System GM650
Rightest Blood Glucose Monitoring System GM300
GE300 Talking Blood Glucose Monitoring System
GE200 Blood Glucose Monitoring System
Bionime Rightest Diabetes Management System
GE Diabetes Management System

Regulation Number: 21 CFR 862.1345

Regulation Name: Glucose test system

Regulatory Class: II

Product Code: NBW, LFR, CGA, JQP

Dated: March 03, 2014

Received: March 6, 2014

Dear Feng-Yu Lee:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Courtney H. Lias -S

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)
k133522

Device Name
GE Diabetes Management System

Indications for Use (Describe)

The GE Diabetes Management System is an over-the-counter software system for use by Health Care Professionals and Patients with diabetes as an aid for managing diabetes. User(s) can transfer blood glucose readings from the following glucose meters: GE100 Blood Glucose Monitoring System with GE PC Link Adaptor (GE GP550), GE300 Talking Blood Glucose Monitoring System with GE PC Link Adaptor for GE300 (GE GP300) and GE200 Blood Glucose Monitoring System with GE PC Link Adaptor (GE GP550) or GE Bluetooth PC Link (GE GP700) to a personal computer for the purpose of viewing, analyzing and printing the blood glucose readings, as well as to backup and to recover users' profile and data.

The GE Diabetes Management System is not intended to provide treatment decisions, nor should it substitute professional opinion. All medical diagnoses and treatment plans should be performed by a licensed health care professional.

Type of Use (Select one or both, as applicable)

☒ Prescription Use (Part 21 CFR 801 Subpart D)

☒ Over-The-Counter Use (21 CFR 801 Subpart C)

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Katherine Serrano -S

Indications for Use

510(k) Number (if known)
k133522

Device Name
Rightest Blood Glucose Monitoring System GM300

Indications for Use (Describe)

The Rightest Blood Glucose Monitoring System GM300 is intended for in vitro diagnostic use (outside of body). It is indicated to be used by professional healthcare personnel or diabetes at home to measure the glucose concentration for aiding diabetes management. The glucose concentration is measured with quantitative capillary whole blood from the fingertip, palm, and forearm by using Rightest Blood Glucose Monitoring System GM300. This device is not intended for testing neonate blood samples.

Special conditions for use statement(s): Rightest System provides plasma equivalent results.

Type of Use (Select one or both, as applicable)

☒ Prescription Use (Part 21 CFR 801 Subpart D)

☒ Over-The-Counter Use (21 CFR 801 Subpart C)

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Indications for Use

510(k) Number (if known)
k133522

Device Name
Rightest Blood Glucose Monitoring System GM700

Indications for Use (Describe)

The Rightest Blood Glucose Monitoring System GM700 is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips, forearm or palm. The Rightest Blood Glucose Monitoring System GM700 is intended to be used by a single person and should not be shared.

The Rightest Blood Glucose Monitoring System GM700 is intended for self testing outside the body (in vitro diagnostic use) by people with diabetes at home as an aid to monitor the effectiveness of diabetes control. The Rightest Blood Glucose Monitoring System GM700 should not be used for the diagnosis of, or screening for diabetes or for neonatal use. Alternative site testing should be done only during steady - state times (when glucose is not changing rapidly).

The Rightest Blood Glucose Test Strips GS700 are for use with the Rightest Blood Glucose Meter GM700 to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips, forearm or palm.

Type of Use (Select one or both, as applicable)

☐ Prescription Use (Part 21 CFR 801 Subpart D)

☒ Over-The-Counter Use (21 CFR 801 Subpart C)

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Katherine Serrano -S

Indications for Use

510(k) Number (if known)
k133522

Device Name
Bionime Rightest Diabetes Management System

Indications for Use (Describe)

The Bionime Rightest Diabetes Management System is an over-the-counter software system for use by Health Care Professionals and Patients with diabetes as an aid for managing diabetes. User(s) can transfer blood glucose readings from the following glucose meters: Rightest Blood Glucose Monitoring System GM550 and GM250 with Rightest PC Link Adaptor (GP550), Rightest Blood Glucose Monitoring System GM700 with Rightest PC Link Adaptor (GP550) or Rightest Bluetooth PC Link (GP700), Rightest Blood Glucose Monitoring System GM650 with Rightest PC Link Adaptor for GM650 (GP650), and Rightest Blood Glucose Monitoring System GM300 with Rightest PC Link Adaptor for GM300 (GP300) to a personal computer for the purpose of viewing, analyzing and printing the blood glucose readings, as well as to backup and to recover users' profile and data.

The Bionime Rightest Diabetes Management System is not intended to provide treatment decisions, nor should it substitute professional opinion. All medical diagnoses and treatment plans should be performed by a licensed healthcare professional.

Type of Use (Select one or both, as applicable)

☒ Prescription Use (Part 21 CFR 801 Subpart D)

☒ Over-The-Counter Use (21 CFR 801 Subpart C)

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Indications for Use

510(k) Number (if known)
k133522

Device Name
GE200 Blood Glucose Monitoring System

Indications for Use (Describe)

The GE200 Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips, forearm or palm. The GE200 Blood Glucose Monitoring System is intended to be used by a single person and should not be shared.

The GE200 Blood Glucose Monitoring System is intended for self testing outside the body (in vitro diagnostic use) by people with diabetes at home as an aid to monitor the effectiveness of diabetes control. The GE200 Blood Glucose Monitoring System should not be used for the diagnosis of, or screening for diabetes or for neonatal use. Alternative site testing should be done only during steady-state times (when glucose is not changing rapidly).

The GE200 Blood Glucose Test Strips are for use with the GE200 Blood Glucose Meter to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips, forearm or palm.

Type of Use (Select one or both, as applicable)

☐ Prescription Use (Part 21 CFR 801 Subpart D)

☒ Over-The-Counter Use (21 CFR 801 Subpart C)

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Indications for Use

510(k) Number (if known)
k133522

Device Name
GE300 Talking Blood Glucose Monitoring System

Indications for Use (Describe)

The GE300 Talking Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips, forearm or palm. The GE300 Talking Blood Glucose Monitoring System is intended to be used by a single person and should not be shared.

The GE300 Talking Blood Glucose Monitoring System is intended for self testing outside the body (in vitro diagnostic use) by people with diabetes at home as an aid to monitor the effectiveness of diabetes control. The GE300 Talking Blood Glucose Monitoring System should not be used for the diagnosis of, or screening for diabetes or for neonatal use. Alternative site testing should be done only during steady - state times (when glucose is not changing rapidly).

The GE300 Blood Glucose Test Strip is for use with the GE300 Talking Blood Glucose Meter to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips, forearm or palm.

Type of Use (Select one or both, as applicable)

☐ Prescription Use (Part 21 CFR 801 Subpart D)

☒ Over-The-Counter Use (21 CFR 801 Subpart C)

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Katherine Serrano -S

Indications for Use

510(k) Number (if known)
k133522

Device Name
Rightest Blood Glucose Monitoring System GM650

Indications for Use (Describe)

The Rightest Blood Glucose Monitoring System GM650 is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips, forearm or palm. The Rightest Blood Glucose Monitoring System GM650 is intended to be used by a single person and should not be shared.

The Rightest Blood Glucose Monitoring System GM650 is intended for self testing outside the body (in vitro diagnostic use) by people with diabetes at home as an aid to monitor the effectiveness of diabetes control. The Rightest Blood Glucose Monitoring System GM650 should not be used for the diagnosis of, or screening for diabetes or for neonatal use. Alternative site testing should be done only during steady - state times (when glucose is not changing rapidly).

The Rightest Blood Glucose Test Strips GS650 are for use with the Rightest Blood Glucose Meter GM650 to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips, forearm or palm.

Type of Use (Select one or both, as applicable)

☐ Prescription Use (Part 21 CFR 801 Subpart D)

☒ Over-The-Counter Use (21 CFR 801 Subpart C)

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